ABSTRACT

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Title of Diploma Thesis: Forced degradation studies of anthelmintics in the process of stability testing of pharmaceuticals

The goals of this thesis were to perform stress tests of selected anthelmintic praziquantel in the preparation process of stability studies of Caniverm®. The samples were exposed to extreme conditions to accelerate the chemical decomposition of a drug substance. The content of active substances and the formation of degradation products were observed. The aims of the tests were to determine the basic properties of a substance or product in model stress situations, simulating the extreme conditions during production, storage, transport and effects of external influences, to characterize degradation products and to verify the suitability of methods for analysis of degradation products. The developed method was partially validated by parameters linearity and precision.

Praziquantel is stable in methanol and water. Degradation product “RP 1” has been formed in the 2% sulfuric acid solution. RP 1 is characterized by retention time of t_R 4.5 min. Degradation product “RP 2” with retention time of t_R 4.9 min has been formed in a 3% hydrogen peroxide solution. Degradation product “RP3”, characterized by retention time of t_R 1.8 min has been formed in an alkaline sodium hydroxide solution. The results of these tests can be used as part of the extended stability tests of Caniverm ® 700 mg tablets.